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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,560

03/18/2004

Tami Harel

34487

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67801 7590 08/08/2007  
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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

08/08/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/804,560

Applicant(s)

HAREL ET AL.

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39-43 and 45-100 is/are pending in the application.
- 4a) Of the above claim(s) 39-43, 45-51, 56-64 and 88-100 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52-55 and 78-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 20061207; 20060919
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 39-43, 45-51, 56-64, and 88-100 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/16/2007.
2. Applicant's election without traverse of claims 52-55 and 78-87 in the reply filed on 5/16/2007 is acknowledged.

### *Priority*

3. The Examiner was unable to find support for the claimed subject matter (i.e. electrifying an electrode when glucose levels are not elevated) in the priority document 60/123,532.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 78-81 and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 78-81 refer to a compensation performed by the apparatus of claim 52. These claims are vague because nothing has

Art Unit: 3762

been set forth to "compensate". The Examiner has interpreted "compensates" to be "significantly reduces or increases blood glucose levels". Appropriate correction is required, including incorporation of language to allow an increase in blood glucose, such as glucagon would provide in claim 80.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 52, 53, 78, 79, and 81-86 are rejected under 35 U.S.C. 102(e) as being anticipated by Houben et al. (US 5,919,216, hereinafter "Houben").

8. In regards to claim 52, Houben discloses an electrode for applying an electric field to the pancreas (104) and circuitry for electrifying the electrode to significantly reduce blood glucose and also apply the field when glucose levels are not elevated (abstract). Since the system also stimulates for a hypoglycemic condition, the system stimulates when glucose levels are not elevated.

9. In regards to claim 53, the system is a closed loop system (abstract), and over-stimulates (i.e. increases burst duration) in cases of doubt (that the patient is hypoglycemic).

Art Unit: 3762

10. In regards to claim 78, the circuitry causes the secretion of an insulin bolus (abstract).

11. In regards to claim 79, the circuitry compensates by reducing glucose in a non-insulin manner (col. 10, line 50). This is considered to be "non-insulin", because a medication, as apposed to insulin, is delivered.

12. In regards to claim 81, the circuitry reduces insulin secretion (col. 9, line 45).

13. In regards to claim 82, the device is programmed with a knowledge of chemical-based insulin therapy provided to said pancreas (col. 10, line 50).

14. In regards to claims 83-85, the device comprises a glucose sensor to determine a need for acute insulin response (col. 7, line 37).

15. In regards to claim 86, the electrode is adapted for attachment to the pancreas (Fig. 10).

### ***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claim 54 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Houben. Houben discloses the essential features of the claimed invention including feedback control every 1 or 2 minutes (col. 7, line 58), inherently providing a semi-open loop system. Alternatively, it is well known in the art to provide semi-open loop systems wherein a relatively long stimulation is applied without feedback to conserve processor resources and battery life when controlling variables that do not require extremely precise control. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Houben's invention by providing a relatively long stimulation without feedback to conserve processor resources and battery life when controlling variables that do not require extremely precise control.

19. Claims 55, 80, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houben. Houben discloses the essential features of the claimed invention except for an open loop system, compensating by reducing glucagon secretion, or an electrode adapted for attachment to a muscular organ. It is well known in the art to provide open loop systems to conserve processor resources and battery life when controlling variables that do not require extremely precise control; to compensate by reducing glucagon levels to modify blood glucose levels faster than by modifying

insulin alone; and to provide an electrode adapted for attachment to a muscular organ to stimulate the pancreas with the easier implantation route of the gastrointestinal tract. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Houben's invention by providing an open loop system to conserve processor resources and battery life when controlling variables that do not require extremely precise control; to compensate by reducing glucagon levels to modify blood glucose levels faster than by modifying insulin alone; and to provide an electrode adapted for attachment to a muscular organ to stimulate the pancreas with the easier implantation route of the gastrointestinal tract.

### ***Conclusion***

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marchal et al. (US 6,853,862) is an example of a teaching of stimulating the pancreas via the gastrointestinal tract, Sun (US 6,122,536) is one of many teachings of modifying glucagon levels to modulate blood glucose levels, and Pfeiler et al. (US 5,558,640) is one of many teachings of open loop control.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

*MWK*  
8/2/07

*George Evans*  
PATENT

9/5/17